UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 20, 2022

MAGENTA THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-38541**	**81-0724163**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

100 Technology Square **Cambridge, Massachusetts**	**02139**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (857) 242-0170

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 Par Value	MGTA	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On December 20, 2022, Magenta Therapeutics, Inc. (the "Company") issued a press release regarding certain clinical updates. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

On December 20, 2022, the Company announced that, per the clinical trial protocol for the MGTA-117 Phase 1/2 Dose Escalation Clinical Trial in relapsed/refractory acute myeloid leukemia ("AML") and myelodysplastic syndrome ("MDS"), it has stopped dosing participants at the Cohort 4 dosing level (0.13 mg/kg) and plans to dose additional participants at the Cohort 3 dosing level (0.08 mg/kg).

Three participants have been dosed in Cohort 4, and dose-limiting toxicities ("DLTs") were observed in the second and third dosed participants. The first participant completed the 21-day DLT observation period with no DLTs. Subsequent to the Company's investor presentation on December 13, 2022, it was reported to the Company that the second dosed participant in Cohort 4 experienced a Grade 4 Serious Adverse Event ("SAE") (respiratory) considered possibly related to MGTA-117. This SAE was later determined to be a DLT and a Suspected Unexpected Serious Adverse Reaction ("SUSAR") due to lung involvement. This participant also experienced Grade 4 aspartate transaminase ("AST") and Grade 3 alanine transaminase ("ALT") elevations without clinically significant changes in bilirubin, gamma glutamyl transferase or alkaline phosphatase. On December 15, 2022, the Company received a report of a respiratory SAE for the third dosed participant. This SAE was subsequently determined to be the second DLT in Cohort 4, thereby triggering prespecified stopping rules for further dosing in Cohort 4. As of the date of this Current Report on Form 8-K, the clinical trial sites have reported that the first participant with a DLT has demonstrated improved respiratory status and AST/ALT enzyme levels, and the second participant with a DLT had improved respiratory status.

Magenta reported the clinical data and other information applicable to the first observed DLT to the U.S. Food and Drug Administration ("FDA") today. Magenta also informed the FDA that the information applicable to the DLT event in the second participant is forthcoming.

In accordance with the clinical trial protocol and following the recommendation of the trial's safety Cohort Review Committee on December 19, 2022, Magenta plans to continue enrollment at the Cohort 3 dose level. As presented at the 2022 American Society of Hematology Annual Meeting on December 12, 2022, no DLTs were observed in the fifteen participants dosed in the first three Cohorts in the clinical trial. Three out of the four participants in Cohort 3 for whom paired bone marrow samples were collected at baseline and post-dosing had depletion of cancer blast cells in both blood and bone marrow. The Company continues to believe that the benefit/risk profile at the Cohort 3 dose level is acceptable to continue enrolling participants in this trial.

Cautionary Note Regarding Forward Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995, as amended. These statements include, without limitation, implied and express statements relating to: Magenta's plans to dose additional participants in the MGTA-117 Phase 1/2 Dose Escalation Clinical Trial in Cohort 3, per the clinical trial protocol; plans to continue enrollment at the Cohort 3 dose level; and Magenta's belief that the benefit/risk profile at the Cohort 3 dose level is acceptable to continue enrolling participants in this trial. Words such as "anticipate," "believe," "continue," "could," "designed," "endeavor," "estimate," "expect," "intend," "may," "might," "plan," "potential," "predict," "project," "seek," "should," "target," "preliminary," "will," "would" and similar expressions are intended to identify forward-looking statements. The express or implied forward-looking statements included in this Current Report on Form 8-K are only predictions and are subject to a number of risks, uncertainties and assumptions, including, without limitation: uncertainties inherent in preclinical and clinical trials and in the availability and timing of data from ongoing and planned clinical and preclinical trials; the ability to initiate, enroll, conduct or complete ongoing and planned preclinical and clinical trials; vulnerability and/or fragility of, and the presence of underlying disorders in, the patient population for the clinical trials of Magenta's product candidates, including the MGTA-117 Phase 1/2 clinical trial in patients with relapsed/refractory AML and MDS; that preliminary data from Magenta's clinical trials may change materially following a more comprehensive review of the data; the delay of any current or planned preclinical or clinical trials, or the delay in development of Magenta's product candidates; whether results from preclinical or earlier clinical trials will be predictive of the results of future trials; interactions with regulatory agencies such as the U.S. Food and Drug Administration; the expected timing of submissions for regulatory approval to conduct or continue trials or to market products; Magenta's ability to successfully demonstrate the safety and efficacy of its product candidates; and risks, uncertainties and assumptions regarding the impact of the continuing COVID-19 pandemic on Magenta's business, operations, preclinical activities, clinical trials, strategy, goals and anticipated timelines. These and other risks are described in additional detail in Magenta's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022 and its other filings made with the Securities and Exchange Commission from time to time. Any forward-looking statements contained in this Current Report on Form 8-K represent Magenta's views only as of today and should not be relied upon as representing its views as of any subsequent date. Magenta explicitly disclaims any obligation to update any forward-looking statements, except to the extent required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits:

The following exhibit relating to Item 7.01 shall be deemed to be furnished, and not filed:

99.1	Press Release dated December 20, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MAGENTA THERAPEUTICS, INC.

Date: December 20, 2022

By: /s/ Stephen Mahoney
Stephen Mahoney
Title: Chief Financial and Operating Officer

Magenta Therapeutics Provides Update for MGTA-117 Phase 1/2 Dose Escalation Clinical Trial

– Cohort 4 Dosing Stopped per Clinical Trial Protocol due to Dose-Limiting Toxicities –

– Plan to Dose Additional Participants in Cohort 3 per Clinical Trial Protocol –

Cambridge, MA – December 20, 2022 – Magenta Therapeutics (Nasdaq: MGTA) today announces that, per the clinical trial protocol for the MGTA-117 Phase 1/2 Dose Escalation Clinical Trial in relapsed/refractory acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS), it has stopped dosing participants at the Cohort 4 dosing level (0.13 mg/kg) and plans to dose additional participants at the Cohort 3 dosing level (0.08 mg/kg).

Three participants have been dosed in Cohort 4, and dose-limiting toxicities (DLTs) were observed in the second and third dosed participants. The first participant completed the 21-day DLT observation period with no DLTs. Subsequent to the Company's investor presentation on December 13, 2022, it was reported to the Company that the second dosed participant in Cohort 4 experienced a Grade 4 Serious Adverse Event (SAE) (respiratory) considered possibly related to MGTA-117. This SAE was later determined to be a DLT and a Suspected Unexpected Serious Adverse Reaction (SUSAR) due to lung involvement. This participant also experienced Grade 4 aspartate transaminase (AST) and Grade 3 alanine transaminase (ALT) elevations without clinically significant changes in bilirubin, gamma glutamyl transferase or alkaline phosphatase. On December 15, 2022, the Company received a report of a respiratory SAE for the third dosed participant. This SAE was subsequently determined to be the second DLT in Cohort 4, thereby triggering prespecified stopping rules for further dosing in Cohort 4. As of the date of this press release, the clinical trial sites have reported that the first participant with a DLT has demonstrated improved respiratory status and AST/ALT enzyme levels, and the second participant with a DLT had improved respiratory status.

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About Magenta Therapeutics

Magenta Therapeutics is a clinical-stage biotechnology company developing medicines designed to bring the curative power of stem cell transplant to more patients with blood cancers, genetic diseases and autoimmune diseases. Magenta is combining leadership in stem cell biology and biotherapeutics development with clinical and regulatory expertise to revolutionize blood and immune reset to allow more patients to take advantage of the curative potential of stem cell transplant and potentially improve eligibility for future gene therapies.

Magenta is based in Cambridge, Mass. For more information, please visit www.magentatx.com.

Follow Magenta on Twitter: @magentatx

Forward-Looking Statements

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following a more comprehensive review of the data; the delay of any current or planned preclinical or clinical trials, or the delay in development of Magenta's product candidates; whether results from preclinical or earlier clinical trials will be predictive of the results of future trials; interactions with regulatory agencies such as the U.S. Food and Drug Administration; the expected timing of submissions for regulatory approval to conduct or continue trials or to market products; Magenta's ability to successfully demonstrate the safety and efficacy of its product candidates; and risks, uncertainties and assumptions regarding the impact of the continuing COVID-19 pandemic on Magenta's business, operations, preclinical activities, clinical trials, strategy, goals and anticipated timelines. These and other risks are described in additional detail in Magenta's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022 and its other filings made with the Securities and Exchange Commission from time to time. Any forward-looking statements contained in this press release represent Magenta's views only as of today and should not be relied upon as representing its views as of any subsequent date. Magenta explicitly disclaims any obligation to update any forward-looking statements, except to the extent required by law.

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